UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC, *et al.*, Plaintiff, v. JOSHUA STEIN, *et al.*, Defendants, and PHILIP E. BERGER and TIMOTHY K. MOORE, Intervenor-Defendants.	**Case No. 1:23-cv-480** **DEFENDANT-INTERVENORS' RESPONSE IN OPPOSITION TO PLAINTIFFS' AMENDED MOTION FOR PRELIMINARY INJUNCTION**

INTRODUCTION

The Supreme Court held in *Dobbs v. Jackson Women's Health Organization* that "[i]t is time to heed the Constitution and return the issue of abortion to the people's elected representatives." 142 S. Ct. 2228, 2243 (2022). Ignoring that instruction, Plaintiffs are abortion providers who disagree with the policy choices behind North Carolina's new abortion laws and seek to constitutionalize their preferences for what North Carolina's laws should be. In doing so, Plaintiffs ask this Court to do what it cannot: "substitute [its] social and economic beliefs for the judgment of" North Carolina's elected

representatives by enjoining two common-sense "health and welfare laws." *Id.* at 2283–84. Because those laws implicate no fundamental right or protected class, are rationally related to North Carolina's legitimate interest in protecting maternal health and safety, and are not unconstitutionally vague, and because Plaintiffs have failed to satisfy the requirements for extraordinary relief, this Court should reject that invitation and deny Plaintiffs' Motion for Preliminary Injunction.

STATEMENT OF FACTS

I. Abortion Safety and Complications

Abortion is dangerous for both a pregnant mother and her unborn child. Dr. Monique Chireau Wubbenhorst is an obstetrician-gynecologist with over twenty years' experience and a researcher at Duke University School of Medicine. She testified in her declaration that abortion safety data is "incomplete" and the complication rate is not low. Decl. of Dr. Wubbenhorst ¶¶ 64, 96, attached as Ex. 1. Each method of abortion performed by Plaintiffs—chemical abortion, aspiration abortion, and dilation and evacuation (D&E) abortion, Farris Decl. ¶¶ 2, 14, ECF No. 49-1—can cause serious, even life-threatening, complications for women. Ex. 1, ¶¶ 7, 9–10, 37, 64, 80.

A. Chemical Abortion

The FDA has approved chemical abortion "for the medical termination of intrauterine pregnancy through 70 days [10 weeks] gestation." FDA Approved Label for Mifepristone (Mifeprex) (Jan. 2023) at 1, attached as Ex. 2 ("FDA Label"). The gestational limitation is based on overwhelming evidence that the risks of chemical abortion to the pregnant mother increase with gestational age. *Id.* at 13. Yet Plaintiffs admit that they provide the drugs off-label "through *11 weeks*" gestation. ECF No. 49-1, ¶ 16. Complications from chemical abortion include incomplete or failed abortion, hemorrhage, "serious and sometimes fatal infections," and even death. Ex. 2, 1–2, 8–9. According to the current FDA label, between 2.9% and 4.6% of women end up in the emergency room due to complications from chemical abortion. *Id.* at 8.

Chemical abortion is contraindicated for women with ectopic pregnancies. *Id.* at 6. An ectopic pregnancy is a pregnancy that occurs outside the uterine cavity. Decl. of Dr. Bane ¶ 58, attached as Ex. 3. Ectopic pregnancies occur in "approximately 2% of all pregnancies," and if left untreated and rupture "can be a life-threatening situation." *Id.* An ectopic pregnancy can only be ruled out by an ultrasound that confirms a pregnancy is inside the uterine cavity, which can be seen beginning around 5 or 6 weeks gestational age. *Id.* ¶¶ 55–58.

B. Aspiration Abortion

Aspiration abortion is a type of surgical abortion that "entails using suction to empty the uterus" and destroy the unborn child. ECF No. 49-1, ¶ 21. Planned Parenthood "provides aspiration abortion up to approximately 14 weeks LMP." *Id.* During an aspiration abortion, the physician inserts a hollow plastic tube into the uterus through the cervix, and sucks the unborn child, placenta, umbilical cord, and gestational sac out with a pump or syringe. *Id.*

Complications include "bleeding, infection, damage to the uterus, possible damage to other organs including bowel and bladder, . . . possible need for further surgery," and even death. Ex. 1, ¶¶ 80, 136. Planned Parenthood expert Dr. Christy M. Boraas Alsleben acknowledges, "[t]he risks associated with abortion increase with gestational age." Boraas Decl. ¶ 27, ECF No. 49-2. While it is impossible to eliminate the risk of complications from aspiration abortion, hospitals are better equipped to treat serious complications. Ex. 3, ¶ 51 ("Hospitals have more resources to manage . . . complications, including intensive care units.").

C. D&E Abortion

Dilation and evacuation abortion is a surgical abortion procedure Plaintiffs use beginning around 14 or 15 weeks LMP ("Last Menstrual Period"). ECF No. 49-1, ¶ 25. During a D&E abortion, the physician first "dilate[] the

patient's cervix," *id.* ¶ 26, and "inserts grasping forceps through the woman's cervix and into the uterus to grab the fetus." *Gonzales v. Carhart*, 550 U.S. 124, 135 (2007). Then, "[t]he doctor grips a fetal part with the forceps and pulls it back through the cervix and the vagina," causing the unborn baby to tear apart. *Id.* This "process of evacuating the fetus piece by piece continues until it has been completely removed." *Id.* at 135–36.

Due to the late gestational age at which D&E abortions are normally performed and the passing of medical instruments multiple times through the patient's cervix, it has a particularly high rate of complications. Ex. 1, ¶ 41 ("Many studies have quantified the association between increasing gestational age and increasing risk for maternal mortality."). Possible complications of D&E abortion include cervical laceration, uterine perforation, hemorrhaging, infection, and even death. *Id.* ¶¶ 152 & Table 3, 188. As with aspiration abortion, performing a D&E abortion in a hospital can reduce, but not eliminate, complications and ensure faster emergency care if they arise. Ex. 3, ¶ 51.

II. Procedural History

Senate Bill 20, "An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs" ("the Act"), as amended by House Bill 190, provides that "[i]t shall be unlawful after the twelfth week

of a woman's pregnancy to procure or cause a miscarriage or abortion in the State of North Carolina." N.C. Gen. Stat. § 90-21.81A(a). "Abortion" is defined to include surgical and chemical abortion. *Id.* § 90-21.81(1). The Act also provides: "[I]t shall not be unlawful to procure or cause an miscarriage or an abortion in the State of North Carolina" (1) "when . . . there exists a medical emergency"; (2) "[d]uring the first 12 weeks of a woman's pregnancy"; (3) "[a]fter the twelfth and through the twentieth week of a woman's pregnancy . . . when the woman's pregnancy is a result of rape or incest"; and (4) "[d]uring the first 24 weeks of a woman's pregnancy, if . . . there exists a life-limiting anomaly." *Id.* § 90-21.81B.

Plaintiffs ask this Court to enjoin two provisions—the hospitalization and IUP documentation requirements. Pls.' Am. Mot. for Prelim. Inj. 1, ECF No. 48. First, the Act provides that "[a]fter the twelfth week of pregnancy, a physician licensed to practice medicine . . . may not perform a surgical abortion as permitted under North Carolina law in any facility other than a hospital." *Id.* § 90-21.82A(b) (eff. Oct. 1, 2023) ("the hospitalization requirement"). Second, the Act provides that "[a] physician prescribing, administering, or dispensing an abortion-inducing drug must . . . [d]ocument in the woman's medical chart the . . . existence of an intrauterine pregnancy." *Id.* § 90-21.83B(a) (eff. July 1, 2023) ("IUP documentation requirement").

ARGUMENT

A preliminary injunction is "an extraordinary remedy [that is] never awarded as of right." *In re Search Warrant Issued June 13, 2019*, 942 F.3d 159, 170 (4th Cir. 2019), *as amended* (Oct. 31, 2019) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008)). To prevail on their preliminary injunction motion, "[P]laintiff[s] must establish that (1) [they are] likely to succeed on the merits, (2) [they are] likely to suffer irreparable harm absent the requested preliminary relief, (3) the balance of the equities weighs in [their] favor, and (4) a preliminary injunction is in the public interest." *Id.* at 170–71. Plaintiffs do not meet any of those requirements here.

I. Plaintiffs cannot prove that the hospitalization requirement and IUP documentation requirement are unconstitutional.

To succeed on a motion for a preliminary injunction, Plaintiffs must make "*a clear showing* that [they are] likely to succeed at trial." *Roe v. Dep't of Def.*, 947 F.3d 207, 219 (4th Cir. 2020), *as amended* (Jan. 14, 2020) (cleaned up) (emphasis added). Plaintiffs failed to make that showing as to either the hospitalization or the IUP documentation requirements.

A. The hospitalization requirement is a legitimate and rational exercise of the State's authority to regulate abortion.

1. The hospitalization requirement satisfies rational basis review.

In *Dobbs*, the Supreme Court held that "rational-basis review is the appropriate standard" for "constitutional challenge[s]" to "state abortion regulations." 142 S. Ct. at 2283. Under rational-basis review, "[a] law regulating abortion . . . is entitled to a 'strong presumption of validity'" and "must be sustained if there is a rational basis on which the legislature could have thought it would serve legitimate state interests." *Id.* at 2284. Plaintiffs concede the Court must evaluate their claims using rational basis review, ECF No. 49, 11, and that the State has a legitimate interest in "the protection of maternal health and safety," *Dobbs*, 142 S. Ct. at 2284; ECF No. 49, 11–12.

Instead, Plaintiffs attempt to skirt *Dobbs* and argue that "the Hospitalization Requirement is not rationally related to any government interest in patient safety." ECF No. 49, 11. In determining whether an abortion regulation is rationally related to a legitimate state interest, "courts cannot 'substitute their social and economic beliefs for the judgment of legislative bodies.'" *Dobbs*, 142. S. Ct. at 2283–84. The pre-*Dobbs* cases cited by Plaintiffs do not say otherwise. ECF No. 49, 11–12. And Plaintiffs wrongfully suggest

that this Court not only can but must defer to "the factual findings" regarding hospital requirements from *overruled* cases. ECF No. 49, 12.

Under rational-basis review, "it is for the legislature, not the courts, to balance the advantages and disadvantages of the new requirement." *Williamson v. Lee Optical of Okla. Inc.*, 348 U.S. 483, 487 (1955). Here, the General Assembly rationally concluded that requiring surgical abortions to be performed in a hospital after 12 weeks would make the procedure safer because hospitals are better equipped to address complications that everyone, including Plaintiffs and their expert witness, agrees arise. Ex. 3, ¶¶ 49, 50, 51, 52; Ex. 1, ¶ 225; ECF No. 49-1, ¶ 41; ECF No. 49-2, ¶¶ 49–52. Surgical abortions can have serious complications, including hemorrhage, infection, cervical laceration, uterine perforation, sepsis, and even death. Ex. 1, ¶ 152 & Table 3.

When these complications occur, hospitals, unlike abortion clinics, have sufficient staffing, systems, equipment, and space to treat complications. *Id.* at ¶ 225. Indeed, patients who suffer any of these complications are typically *transferred* to a hospital. *Id.* at ¶¶ 189, 191. The General Assembly reasonably concluded that it is safer for the patient to start at the hospital where necessary staff and equipment are already on hand.

Plaintiffs argue that the hospitalization requirement is irrational because "[s]erious complications . . . are vanishingly rare." ECF No. 49, 13; ECF No. 49-1, ¶ 31. But they admit that "serious complications do arise" that require them "to safely transfer the patient a hospital." *Id.* That confession alone satisfies rational-basis review. That Plaintiffs disagree with the General Assembly's safeguards does not make them irrational. To articulate Plaintiffs argument is to defeat it—the Constitution does not prohibit second-trimester surgical abortions to be performed in a hospital.

Plaintiffs next argue that the hospitalization requirement is irrational because data establishes "beyond any doubt the safety of outpatient abortions." ECF No. 49, 13. That is simply untrue, and Plaintiffs admit that some patients end up in the hospital due to serious, even life-threatening, complications ECF No. 49, 6, 13; ECF No. 49-1, ¶ 43. Again, there is no dispute that hospitalization will be necessary for at least *some* women who suffer complications during surgical abortions. It is not irrational to require safety precautions to protect these women who suffer serious complications during a surgical abortion.

Further, data on the safety of abortion is "severely flawed." Ex. 1, ¶¶ 96, 98, 101. The General Assembly has "wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales*, 550 U.S. at 163. Plaintiffs may dislike the way elected officials interpreted the entirety of the

evidence and reached a result different from the one Plaintiffs advocate, but that does not make the General Assembly's different policy choices constitutionally irrational.

Nor does it matter that "major medical associations" disagree with North Carolina's conclusion that hospitalization makes second-trimester abortions safer. ECF No. 49, 13. It is squarely within the State's traditional power to protect the pregnant women that Plaintiffs admit *will* require hospitalization. Indeed, the Supreme Court has twice rejected the claim that a state must defer to differing policy choices advocated by voluntary medical associations. First, in *Gonzales*. 550 U.S. at 170–71 (Ginsburg, J., dissenting) (criticizing the majority for "tolerat[ing] . . . federal intervention to ban a nationwide procedure found necessary and proper in certain cases by the American College of Obstetricians and Gynecologists").

And second in *Dobbs*. *See* Brief for Am. Coll. of Obstetricians and Gynecologists, et al. as Amici Curiae Supporting Respondents 22–23, *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022) (No. 19-1392), 2021 WL 4312120 at * 21–23 (citing "medical consensus" to argue the State's conclusion that its law promoted the health and safety of women was without "legitimate scientific basis")."The day is gone when" courts "use[d] the Due Process Clause of the Fourteenth Amendment to strike down state laws" regulating abortion

because the challenger believes them to be "unwise, improvident, or out of harmony with a particular school of thought." *Lee Optical*, 348 U.S. at 488. The Court should not be persuaded by any argument to the contrary.

Plaintiffs also told the Court that "fewer complications from abortion are seen in settings that perform higher volumes of those procedures." ECF No. 49, 13 (citing ECF No. 49-1, ¶¶ 38, 74). But Dr. Farris cites no scientific studies for this point. ECF No. 49-1, ¶ 38 & n.29. Instead, she cites an article from U.S. News and World Report, Steve Sternberg & Geoff Dougherty, *Risks are High at Low-Volume Hospitals*, U.S. News & World Rep. (May 18, 2015, 12:01 A.M.), https://www.usnews.com/news/articles/2015/05/18/risks-are-high-at-low-volume-hospitals, that does not even *mention* abortion. Instead, it compares high volume hospitals to low volume hospitals—not hospitals to outpatient clinics. And here, Plaintiffs admit "serious complications do arise" that require them "to safely transfer the patient a hospital." ECF No. 49, 13; ECF No. 49-1, ¶ 31. When such complications occur, hospitals have the necessary staff and equipment to treat them. Ex. 1, ¶ 225. It is not irrational for the General Assembly to conclude that it is safer for a patient to start at the hospital where life-saving staff and equipment are already on hand.

Under the Constitution, state legislation must be upheld if it is rationally related to a legitimate state interest. At day's end, Plaintiffs utterly fail to meet

their burden of establishing that the hospitalization requirement is not rationally related to North Carolina's legitimate interest in women's health and safety. It is hardly irrational for the General Assembly to determine that a hospital is the best place for a procedure that causes life-threatening emergencies that require Plaintiffs to transfer patients to those very same hospitals. At most, Plaintiffs could accuse the law of being safer than they think it needs to be, but that is not irrational. For these reasons, the hospitalization requirement passes muster under rational basis review, and the Court should reject Plaintiffs' arguments.

2. The hospitalization requirement does not violate the Equal Protection Clause.

The Supreme Court held in *Dobbs* that "laws regulating or prohibiting abortion are not subject to heightened scrutiny" under the Equal Protection Clause. *Dobbs*, 142 S. Ct. at 2246. "Rather, they are governed by the same standard of review as other health and safety measures": the rational-basis test. *Id.* at 2246, 2283; *see also In re Premier Auto. Servs., Inc.*, 492 F.3d 274, 283 (4th Cir. 2007) (same).

Plaintiffs argue that the hospitalization requirement violates equal protection for two reasons: (1) "[i]t irrationally singles out physicians who provide and patients who seek abortion . . . as compared to those providing and seeking medical procedures of equal or greater risk," ECF No. 49, 9; and (2) it

applies "only to survivors of rape or incest and patients with grave fetal diagnoses," *id.* at 14. But the hospitalization requirement turns on gestational age, N.C. Gen. Stat. § 90-21-82A (C), a factor which even Plaintiffs admit increases risk. ECF No. 49-2, ¶ 27. Nothing in the law distinguishes between a particular class of *patients* (who may seek medical services aside from second-trimester abortion outside a hospital) or a class of *physicians* (who may perform gynecological procedures aside from second-trimester abortion outside a hospital). *See* ECF No. 49-1, ¶ 3 (listing non-abortion medical services that Dr. Farris performs).

Nothing in the law prevents abortion providers from obtaining privileges to perform abortions in hospitals after 12 weeks. Indeed, Plaintiff Dr. Gray does this. Because any provider may seek to perform abortions in a hospital and there is no disparate treatment.

Nor does the hospitalization requirement distinguish as to classes of patients: it applies to surgical abortions from 12–20 (or 24) weeks' gestational age. N.C. Gen. Stat. § 90-21-82A (C). North Carolina law does not violate the Equal Protection Clause because it distinguishes between "suitable facilit[ies]" based on the gestational age of the fetus and attendant risks, not a class of provider or patient. *See id.* §§ 90-21.81B, 90-21.82A.

Even before *Dobbs*, the Fourth Circuit upheld a South Carolina law distinguishing between performing an abortion at different types of facilities against an equal protection challenge, explaining that "[t]he rationality of distinguishing between abortion services and other medical services when regulating physicians or women's healthcare has long been acknowledged by Supreme Court precedent." *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 173 (4th Cir. 2000). Plaintiffs do not even mention *Bryant*, relying instead on pre-*Dobbs* out-of-circuit cases. *See* ECF No. 49, 9–10. But *Bryant* controls.

Plaintiffs next argue that the Act violates the Equal Protection Clause because miscarriage management using the same procedures can sometimes occur outside the hospital. ECF No. 49, 10–11. Again, that has no bearing on equal protection because the law regulates medical procedures, not protected classes of people. And it is well established that the legislature need not deal with every conceivable risk at once. *Lee Optical*, 348 U.S. at 489. Further, the Supreme Court has long held that "[a]bortion is inherently different from other medical procedures, because no other procedure involves the purposeful termination of a potential life." *Harris v. McRae*, 448 U.S. 297, 325 (1980); *see also Dobbs*, 142 S. Ct. at 2258.

In a last-ditch effort to wrench this law into a heightened scrutiny analysis, Plaintiffs claim that second-trimester surgical abortion "is as safe as"

other medical procedures that are performed outside of hospitals—procedures like "vasectomies, colonoscopies, wisdom tooth extraction, and tonsillectomies." ECF No. 49, 10. That claim is simply untrue. Ex. 1, ¶¶ 153–66. Regardless, the legislature "may take one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind." *Lee Optical*, 348 U.S. at 489. So even if Plaintiffs' claim is accepted on its face, it still fails—the Constitution doesn't require the General Assembly to make medical procedures safer all at once just because it chooses to make abortion safer.

Finally, Plaintiffs argue that the hospitalization requirement "makes accessing abortion even more challenging for people already facing personal hardship due to the circumstances of their pregnancies." ECF No. 49, 14. Even if Plaintiffs offered admissible opinions on this and were qualified to do so (they do not and are not) that does not state an Equal Protection violation. Under *Dobbs*, any alleged "burden" is a policy issue for the legislature to assess. 142 S. Ct. at 2272–73. Further, the hospitalization requirement is rationally designed to *protect* women who are at increased risk because of the gestational age of their unborn child. Plaintiffs provide no evidence that the requirement is motivated by "a bare desire to harm" such patients. ECF No. 49, 15. For these reasons, the hospitalization requirement passes muster under the Equal Protection Clause, and the Court should reject Plaintiffs' contrary arguments.

B. The IUP documentation requirement satisfies rational basis review.

The IUP documentation requirement provides that "[a] physician prescribing, administering, or dispensing an abortion-inducing drug must . . . [d]ocument in the woman's medical chart the . . . existence of an intrauterine pregnancy." N.C. Gen. Stat § 90-21.83B(a). Plaintiffs argue that this requirement is "unconstitutionally vague" and "irrational in violation of the Due Process Clause." ECF No. 49, 9. Plaintiffs fail to show a likelihood of success on the merits of either claim.

1. The IUP documentation requirement is not vague.

A statute is unconstitutionally vague only if it fails to "give a person of ordinary intelligence adequate notice of what conduct is prohibited." *Manning v. Caldwell for City of Roanoke*, 930 F.3d 264, 272 (4th Cir. 2019) (en banc). So long as a statute includes "sufficient standards to prevent arbitrary and discriminatory enforcement," it survives a vagueness challenge. *Id.*; *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972) (adequate notice where terms are "clearly defined").

Where, as here, the challenged law does not implicate a fundamental right, "speculation about possible vagueness in hypothetical situations . . . will not support a facial attack on a statute when it is surely valid 'in the vast majority of its intended applications.'" *Hill v. Colorado*, 530 U.S. 703, 733

(2000) (citing *United States v. Raines*, 362 U.S. 17, 23 (1960)). And while "the standard of certainty is higher" "where a challenged statute 'imposes criminal penalties,'" *Carolina Youth Action Project v. Wilson*, 60 F.4th 770, 781 (4th Cir. 2023), the State still need not show that the challenged statute is written with "mathematical precision," *Greenville Women's Clinic v. Comm'r, S.C. Dep't of Health & Env't*, 317 F.3d 357, 366 (4th Cir. 2002).

Here, the IUP documentation requirement does not implicate a fundamental right. *See Dobbs*, 142 S. Ct. at 2242 ("The Constitution makes no reference to abortion, and no such right is implicitly protected by any constitutional provision."); *see also Planned Parenthood of Ind. & Ky., Inc. v. Marion Cnty. Prosecutor*, 7 F.4th 594, 603 (7th Cir. 2021) ("[C]ourts have looked with disfavor on facial vagueness challenges to statutes that do not implicate fundamental rights."). And while the IUP documentation requirement gives rise to both civil and criminal penalties, N.C. Gen. Stat. §§ 14-44, 14-45, 14-23.2, 90-21.88, 90-21.88A, each of the possible criminal penalties include a scienter requirement, *id.* §§ 14-23.2 (a)(1) ("willfully and maliciously"), 14-44 ("willfully"), 14-45 ("with intent"). These scienter requirements help "ameliorate[]" any heightened concerns due to the requirement's criminal prohibitions. *Hill*, 530 U.S. at 732.

The Act is not ambiguous: it provides that chemical abortion within the first 12 weeks of a woman's pregnancy are lawful only if the "physician prescribing, administering, or dispensing an abortion-inducing drug" first "document in the woman's medical chart the . . . existence of an intrauterine pregnancy." N.C. Gen. Stat. § 90-21.83B(a). This requirement is not subject to misinterpretation: it provides that a doctor can perform a chemical abortion through twelve weeks LMP, but only if they first document IUP. To read the statute otherwise would render the requirements of section 90-21.83B superfluous. *See United States v. Simms*, 914 F.3d 229, 241 (4th Cir. 2019) ("[W]e cannot adopt a reading of [a statute] that renders part of the statute superfluous over one that gives effect to its 'every clause and word.'").

Plaintiffs' vagueness challenge fails because the IUP documentation requirement "give[s] a person of ordinary intelligence adequate notice of what conduct is prohibited." *Manning*, 930 F.3d at 272. Its terms are "clearly defined." *Grayned*, 408 U.S. at 108. In fact, Plaintiffs do not even argue they cannot understand any specific term, but instead that the IUP documentation requirement "is ambiguous as to whether a provider who cannot comply with the documentation requirement" because "an intrauterine embryo cannot yet be detected by an ultrasound" is "prohibited" from performing a chemical

abortion. ECF No. 49, 17–18. Plaintiffs elide disagreement with vagueness, but the two are not equivalent.

A physician must use ultrasound to determine whether a pregnancy is intrauterine. Ex. 1, ¶ 254; Ex. 3, ¶ 60. Plaintiffs know this. *See* ECF No. 49, 17 (admitting that "document[ing] . . . the . . . existence of an intrauterine pregnancy" is "an impossibility . . . in the early weeks of pregnancy, where an intrauterine embryo cannot yet be detected by ultrasound"). This is not vague. Plaintiffs' dislike of the documentation requirement cannot provide grounds for this Court to hold an unambiguous statute unconstitutional.

Similarly, the IUP documentation requirement leaves no room for "arbitrary and discriminatory enforcement." *Manning*, 930 F.3d at 272. All a state official need do to determine whether the statute has been violated is check the "woman's medical chart" to see whether the physician "[d]ocument[ed] . . . the existence of an intrauterine pregnancy." N.C. Gen. Stat § 90-21.83. This is hardly a situation where a statute "specifies no standard of conduct." ECF No. 49, 18. Plaintiffs understand exactly what conduct is prohibited: performing a chemical abortion without documenting an intrauterine pregnancy. For these reasons, Plaintiffs have not shown a likelihood of success on the merits of their vagueness claim.

2. The IUP documentation requirement is rational.

Like the hospitalization requirement, the IUP documentation requirement is rationally related to the State's interest in "the protection of maternal health and safety," *Dobbs*, 142 S. Ct. at 2284. The IUP documentation requirement protects women's health by ensuring that physicians do not prescribe chemical abortion drugs to a woman suffering from an ectopic pregnancy. Ex. 3, ¶ 58. Critically, the FDA's warning label for mifepristone—the first drug in the chemical abortion regimen—states that the "[a]dministration of [mifepristone] and misoprostol for the termination of pregnancy . . . is contraindicated in patients with . . . [c]onfirmed or suspected ectopic pregnancy." *See* Ex. 2, 4.

The label also instructs that Mifepristone "is not effective for terminating ectopic pregnancies." *Id.* at 6. Untreated ectopic pregnancy can cause serious injury and even death if left untreated. Ex. 1, ¶¶ 246, 255 ("Ectopic pregnancy is the leading cause of first trimester maternal death . . . ectopic pregnancy . . . causes substantial morbidity and mortality."); Ex. 3, ¶ 58. Thus, "[h]ealthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a

medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy." Ex. 2, 6.

The only way to definitively diagnose ectopic pregnancy is by ultrasound, which can effectively show this beginning at about five or six weeks LMP. Ex. 1, ¶ 254 ("No determination that is not based on ultrasound and quantitative (blood) pregnancy testing can rule out ectopic pregnancy"); Ex. 3, ¶¶ 55, 58. Ectopic pregnancy is contraindicated for chemical abortion. The General Assembly rationally concluded that requiring documentation of an intrauterine pregnancy would prevent serious health consequences to women with undiagnosed ectopic pregnancies. The State has a longstanding, well-founded right to legislate for safety purposes and ensure that no woman who has an ectopic pregnancy (even those early in pregnancy) receive unapproved and dangerous drugs that could hurt her.

Plaintiffs suggest that their screening process—merely "asking questions about the patient's medical history and current symptoms," ECF No. 49, 19—adequately mitigates this risk. But some women suffering from ectopic pregnancies are asymptomatic for a long portion of the disease progression. Ex. 1, ¶ 352. This means that some women Plaintiffs screen and consider low risk for ectopic pregnancy suffer from the condition. Plaintiffs admit they would give chemical abortion drugs to such women. That is dangerous.

Nor is it safe to "*simultaneously* provide[] the medication abortion *and* conduct further testing using serial blood draws," ECF No. 49, 19 (emphasis added), because that protocol fails to rule out contraindications *before* prescribing dangerous abortion drugs, Ex. 1, ¶¶ 248–76. Dr. Farris admits that the test results can take up to 24 hours. That means that Dr. Farris has already administered the chemical abortion drugs to the patient and sent her home before any lab test suggesting an ectopic pregnancy is possibly available. And even if the lab results show a higher risk of ectopic pregnancy, Plaintiffs have no way to guarantee she will return to the clinic for additional lab testing or surgical abortion. Leaving aside the inconsistency of Plaintiffs' position that making an additional visit for follow up care is "prohibitive for some patients," ECF No. 49-1, ¶¶ 42, 54–55, such patients face serious injury and even death.

Indeed, the FDA medication label for mifepristone notes, "some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy," Ex. 2, 6. This means a woman may misinterpret her hemorrhaging due to a ruptured ectopic pregnancy as a normal side effect of the chemical abortion drugs. S.H. Jayanth, *et al.*, *Fatal Ruptured Ectopic Pregnancy—A Case Report*, 87 Medico-Legal J. 38, 38–41 (2019). Starting October 1, women in North

Carolina suffering from ectopic pregnancy will benefit from the law's protections.

Plaintiffs complain that "[r]eferring a patient for ectopic evaluation instead of providing a medication abortion . . . does not lead to earlier or more accurate diagnosis of ectopic pregnancy." ECF No. 49, 20. Even if that were true, which it is not, this has no bearing on the law. The IUP documentation requirement neither commands nor prevents a physician from "referring a patient for ectopic evaluation." Instead, it quite simply requires a physician to conduct an evaluation to identify the presence of an intrauterine pregnancy themselves *before* prescribing dangerous chemical abortion drugs that are contraindicated when a patient is suffering from an ectopic pregnancy. *See* N.C. Gen. Stat § 90-21.83B(a)(7). The point is this: no patient should get chemical abortion drugs before a physician has ensured the patient is not suffering from an ectopic pregnancy.

Plaintiffs further argue that the requirement is irrational because "any patient who is denied a medication abortion under [the IUP documentation requirement] could still. . . obtain a procedural abortion." ECF No. 49, 20. But the fact that very few surgical abortions occur before five or six weeks LMP is a sufficient rational basis for that distinction. Further, the legislature "may take one step at a time, addressing itself to the phase of the problem which

seems most acute to the legislative mind." *Lee Optical*, 348 U.S. at 489. Indeed, the legislature had the unfettered ability to outright ban all abortion under *Dobbs*, so anything less than that is certainly within its purview.

For these reasons, the IUP documentation requirement satisfies rational basis review.

II. Planned Parenthood has not shown it will suffer irreparable harm absent an injunction.

To obtain a preliminary injunction, "a plaintiff must demonstrate more than just a 'possibility' of irreparable harm." *Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017). Rather, the "plaintiff must make a clear showing of irreparable harm, and the required irreparable harm must be neither remote nor speculative, but actual and imminent." *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 283 (4th Cir. 2002) (cleaned up).

Plaintiffs have not made that showing here: the Act does not irreparably harm Dr. Gray, Planned Parenthood, its physicians, or its patients because the Act does not deprive them of any constitutional rights as discussed above. Moreover, the supposed "burdens" imposed are both overstated and irrelevant under *Dobbs* because Plaintiffs' patients have no constitutional right to abortion. *Dobbs*, 142 S. Ct. at 2242. If North Carolina may constitutionally serve its interests in protecting fetal life and women's health by prohibiting

abortion entirely, it may constitutionally govern the circumstances under which an abortion can be performed.

Plaintiffs argue the Act will "harm Plaintiffs and their patients by delaying . . . and even, at times, denying—necessary health care." ECF No. 49, 21. But the challenged requirements do not deny women abortions; abortions in North Carolina are lawful before twelve weeks, including chemical abortions, so long as the physician follow the safety rules about ectopic pregnancy and after twelve weeks so long as the abortion fits into one of the statutory exceptions and occurs in a hospital. *See* N.C. Gen. Stat. §§ 90-21.81B, 90-21.82A, 90-21.83B. Further, most abortions are performed after five or six weeks (when the pregnancy is first visible by ultrasound). Ex. 1, ¶ 241. As Dr. Farris admits, many women do not even know that they are pregnant until around six weeks. ECF No. 49-1, ¶ 80.

Second, the Act recognizes the difficulty and heartbreak involved for survivors of sexual violence and patients with life-limiting fetal diagnoses by specifically *allowing* abortion up to 20 weeks LMP in cases of "rape or incest" and up to 24 weeks LMP in cases of "lethal fetal anomaly." N.C. Gen. Stat. § 90-21.81B. "Hospitals and emergency departments are trained" to provide the "intense medical and psychological support" that rape or incest victims need and to "ensure the forensic chain of evidence is followed," so that the

rapist may face justice. Ex. 3, ¶ 52. It is not irrational for the General Assembly to think that a hospital is the safest place for second-trimester surgical abortions.

Nor is the Act "an attack on families with low incomes, North Carolinians of color, and rural North Carolinians." ECF No. 49, 22. On the contrary, these groups deserve safe health care as do all North Carolinians. The General Assembly has determined that abortion is lawful within the first 12 weeks LMP (and longer for certain exceptions) and instituted modest and rational safety regulations. Moreover, the Act specifically addresses concerns of low-income North Carolinians by appropriating "$3,500,000[] in recurring funds for each year . . . to be used to award grants to local health departments and nonprofit community health centers" and "2,800,000[] in recurring funds" to Medicaid benefits relating to pregnancy and prenatal care. Ex. 4, SB 20 §§ 4.1, 4.2(a)–(c).

For these reasons, neither Dr. Gray, Planned Parenthood, its physicians, nor its patients will suffer irreparable harm absent an injunction.

III. The balance of the equities and the public interest weigh against enjoining the challenged provisions.

When balancing the equities, a court should "focus[] specifically on the concrete burdens that would fall on the party seeking the injunction [and] pay particular regard for the public consequences in employing the extraordinary

remedy of injunction." *Dep't of Defense*, 947 F.3d at 231. Here, both the balance of the equities and the public interest weigh against Plaintiff's proposed preliminary injunction.

At the outset, North Carolina will "suffer[] a form of irreparable injury" if this Court "enjoin[s]" it "from effectuating" the challenged provisions, which were "enacted by representatives of its people." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (citing *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977)). Moreover, "the public interest is . . . served by permitting legitimate and duly enacted legislation," including the challenged provisions, "to be enacted." *N.C. State Conf., of the NAACP v. McCrory*, 156 F. Supp. 3d 683, 708 (M.D.N.C. 2016); *see also Priorities USA v. Nessel,* 860 F. App'x 419, 423 (6th Cir. 2021) (holding the public interest necessarily weighs against enjoining a duly enacted statute); *Carson v. Simon*, 978 F.3d 1051, 1061 (8th Cir. 2020) (holding "[t]he public interest is likewise served by maintaining the ability to enforce the law adopted by the . . . Legislature and in upholding the exclusive authority vested in the . . . Legislature").

A preliminary injunction would not "preserve North Carolinians' health and safety." ECF No. 49, 23. Quite conversely, as detailed above and in the attached declarations, the challenged provisions serve to make abortion *safer* for the mother. For example, they ensure that abortion providers do not provide

contraindicated chemical abortion drugs to a woman suffering from an ectopic pregnancy without first determining whether she suffers from an ectopic pregnancy. And they ensure that admittedly higher-risk later-term abortions take place in a hospital where even Plaintiffs agree they send patients when certain complications arise. Regardless, the Constitution "give[s] state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales*, 550 U.S. at 163. Thus, the balance of the equities and the public interest support the State, and the Court should deny Plaintiffs' Motion.

CONCLUSION

This Court should deny Plaintiffs' Motion for Preliminary Injunction.

RESPECTFULLY SUBMITTED THIS 7th day of August 2023.

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*** *Notice of Special Appearance Filed*

CERTIFICATE OF SERVICE

I hereby certify that on August 7, 2023, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send a notice of electronic filing to all counsel of record.

s/ W. Ellis Boyle
W. Ellis Boyle

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing document complies with L.R. 7.3(d) and contains less than 6,250 words. I also certify that this document uses 13-point Century Schoolbook and has a top margin of 1.25" on each page in compliance with L.R. 7.1(a).

s/ W. Ellis Boyle
W. Ellis Boyle